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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,262	08/27/2003	Yerramilli V.S.N. Murthy	027585-000801US	6595
20350 7590 09/12/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 09/12/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/650,262	Applicant(s) MURTHY ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,44 and 59-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,44 and 59-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 4, 2008 has been entered.

Claims 1, 3-14, 44 and 59-70 are pending in this application.

Applicants' arguments filed April 4, 2008 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-8, 11, 12, 14, 44, 59-64, 67, 68 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel et al. U.S. Patent No. 6,309,663 B1.

Art Unit: 1614

Patel et al. teach a pharmaceutical composition for oral or parenteral use (column 41, lines 44-54) comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). It differs in that it does not specifically identify the components and “lipophilic counter ions”, “water immiscible solvents” or “clear solutions”. However, “Products of identical chemical composition (i.e. decanoic acid/lipophilic counter ion) can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims (i.e. the release of the active compound over time) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). It would have been made obvious to one of ordinary skill in art at the time it was made to combine an active agent such as gentamycin and fluoxetine (see column 30, lines 3 and 36) with a water immiscible solvent such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37). motivated by the teaching of Patel et al. that the composition is a successful carrier for oral and injectable agents.

Double Patenting

Art Unit: 1614

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 3-14, 44 and 59-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 10-12, 17-19, 27-30 and 38-41 of U.S. Patent No. 7,033,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because The instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires di-lauric acid salt of tilmicosin and a pharmaceutically acceptable solvent wherein at least a portion of the di-lauric acid salt of tilmicosin is dissolved in the solvent. None of the instant claims recites that specific combination, but instant claims 1, 3-14, 44 and 59-70 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner.

Art Unit: 1614

One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 1, 3-14, 44 and 59-70 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-10 and 14-19 of U.S. Patent No. 7,404,964. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires a composition comprising a salt comprising a pharmaceutically active compound and a lipophilic counter ion and a pharmaceutically acceptable solvent wherein the salt and the solvent form a solution. Instant claims 1, 3-14, 44 and 59-70 are broadly inclusive thereof because they are inclusive of a pharmaceutically active compound and a lipophilic counter ion and a pharmaceutically acceptable immiscible solvent. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

Claims 1, 3-14, 44 and 59-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13-20 and 32-35 of copending Application No. 10/974833. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 1 requires a composition comprising a sustained release composition comprising a proton donating pharmacologically active ingredient and a proton accepting pharmacologically active ingredient and a non-aqueous solvent in an injectable form that releases over time. Instant claims 1, 3-14, 44 and 59-70 are broadly inclusive thereof because they are inclusive of a composition wherein a salt is formed of a pharmaceutically active compound (proton donator) and a lipophilic counter ion (proton acceptor) and a pharmaceutically acceptable immiscible solvent (non-aqueous) in an injectable form that releases the active compound over time. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 3-14, 44 and 59-70 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 65-138 of copending Application No. 11/088922. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and conflicting claims recite substantially the same subject matter, differing only in the description of the particular components claimed. For instance, conflicting claim 65 requires an active agent, a lipophilic counter ion and a pharmaceutically acceptable solvent; however, the claims contain the same elements as recited in the instant claims, e.g., active agents such as tilmicosin, lipophilic counter ions such as decanoic acid and solvents such as linoleic acid. The instant claims require elements such as e.g. active agents such as tilmicosin, a lipophilic counter ion such as decanoic acid and a water immiscible solvent such as linoleic acid (note linoleic acid is listed in the instant claims as a lipophilic counter ion and as a water immiscible solvent). None of the instant claims recites that specific combination, but instant claims 1-14 and 44-70 are broadly inclusive thereof. It would have been obvious to anyone of ordinary skill in the art that the claims overlapped in scope in this manner. One skilled in the art would have been motivated to have interpreted the claims as broadly as is reasonable, and in doing so recognize that they are coextensive in scope and thus the proper subject of an obviousness-type double patenting rejection as outlined by *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical composition, the

Art Unit: 1614

properties applicant discloses and/or claims (i.e. water immiscible solvent and lipophilic counterion) are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant traverses the rejection of Patel et al. and asserts that Patel et al. discloses a triglyceride-free pharmaceutical system having a dosage form of an absorption enhancing composition comprising at least two surfactants, at least one of which is hydrophilic and a hydrophobic therapeutic agent. In response, the claim language *comprising* leaves the claim open for the inclusion of unspecified ingredients, even in major amounts and as such, does not exclude the surfactants of Patel et al. Patel et al. teach a pharmaceutical composition for oral or parenteral use (column 41, lines 44-54) comprising active agents such as gentamycin (antibiotic) and fluoxetine (column 30, lines 33 and 36) combined with hydrophobic surfactants (water immiscible solvent) such as castor oil, palm kernel oil and corn oil (see table 5, columns 11-12) and ionizable surfactants that are in their ionized form (column 24, lines 23-27) such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37).

Applicant states that the ionizable surfactants such as oleic acid, capric acid (decanoic acid), linoleic acid and lauric acid (column 24, lines 34-37) are part of a “laundry list” of active compounds. In response, when the species is clearly named, the

Art Unit: 1614

species claim is anticipated no matter how many other species are additionally named.

Ex parte A, 17. USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. *The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught.* The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. 102(a), in that publication.'). *Id.* at 1718. See also *In re Simvaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)." In this case, the species "ionizable surfactants" are clearly named, although applicant has employed a different nomenclature (lipophilic counter ions).

Regarding the assertion that the salt is formed in instant claims 1 and 44, it is unclear to the Examiner that the salt is formed together. The claims state that "a salt formed of the pharmacologically active compound and a lipophilic counter ion and a pharmaceutically acceptable water immiscible solvent". It appears to the Examiner that the salt is formed with the pharmacologically active compound and that the lipophilic counter ion is added to the salt that is already formed. It is suggested that the claims be amended to more clearly set forth that the salt formation results from the combination of the pharmacologically active compound and the lipophilic counter ion.

Regarding the assertion that Patel et al. teaches away by the assertion that the composition is absorption enhancing, the intended use must result in a structural difference between the claimed invention and the prior art in order to patentably

Art Unit: 1614

distinguish the claimed invention from the prior art. There does not appear to be a structural difference between the composition of Patel et al. and the instant claims with the exception of functional language. Since the compositions of the patent are capable of performing the intended use of releasing the composition over time, then it meets the claim. The biological half-life of a substance is the time it takes for a substance (drug, radioactive nuclide, or other) to lose half of its pharmacologic activity. As noted in the Physicians Desk Reference (PDR), fluoxetine has an elimination half life of 1 to 3 days. As such, the composition of Patel would be present in the body of the patient for at least 1 to 3 days with acute administration and 4 to 6 days with chronic administration (see page 3 of PDR).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

It is not clear to the Examiner what picking and choosing is needed in order to determine what medicaments are specifically described in Patel et al. to determine which agents are included as part of the invention. All that is needed to implement the disclosure of Patel et al. is to combine any of the agents recited (the patent is drawn to

Art Unit: 1614

formulation of selected hydrophilic agents that have poor bioabsorption) with the water immiscible solvents recited along with a decanoic acid. There does not appear to be any difficulty in arriving at the decision of which agent to choose.

Regarding the non-statutory obviousness-type double patenting rejection over claims 65-138 of co-pending 11/088,922, applicant has requested that the rejection be held in abeyance until all rejections of the claims over prior art have been addressed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Friday from 8:00 A.M. - 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/650,262
Art Unit: 1614

Page 12

Donna Jagoe /D. J./
Examiner
Art Unit 1614

September 9, 2008

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614